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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,818	02/27/2004	Daniel E. Beedon	CLS 6006	7979

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EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/788,818

Applicant(s)

BEEDON ET AL.

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to applicant's communication of 5/23/2006.
Currently claims 1-19 are pending and stand rejected below.

Response to Arguments

Applicant's arguments filed 5/23/2006 have been fully considered but they are not persuasive.

Applicant argues that Sawa does not disclose "threads with major and minor diameters, wherein the first and second mating members are smaller than the major and minor diameters of the other first and second mating members". Applicant further argues that the horizontal contour lines (unnumbered in figure 2) were mistakenly referred to by examiner as disclosing the applicant's claim. It is Examiner's position that the unnumbered plunger and rod threads (not contour lines) have major and minor diameters, wherein the major and minor diameters of one of the first and second mating members are smaller than the major and minor diameters of the other of the first and second mating members (examiner draws applicant's attention to the polygonal-shaped male and female threads of the rod and mating plunger, and 3D shaped groove lines).

Applicant further argues that the 103 rejections with Scheiner et al. is improper because Scheiner teaches the coating of PARYLENE to provide a non-thrombogenic encapsulate moisture barrier and insulate, important properties for a piston. It is well known in the art that PARYLENE has many unique and useful properties. The use of PARYLENE thin film conformal coatings can be deposited on most biomedical devices,

or substrates. The coated PARYLENE substrates or devices are stable, and show little or no change in their response characteristics. When coated with PARYLENE (an accepted biomedical compatible coating) the device or substrate is chemically isolated and compatible with its environment. Some typical applications are forming Mandrels, Catheters, Guide Wires, Stents, Sensors, Transducers and Probes. All of which have been used or implanted and found to be compatible with body tissue. Further PARYLENE is a dry film lubricant useful on a rubber element that cannot accept the contamination levels and high particle counts caused by silicon oils, etc. It would be well known in the medical devices art to form biocompatible devices with PARYLENE both for its encapsulate properties as well as its lubrication abilities, and all other PARYLENE properties.

In response to applicant's argument that Scheiner is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

In this case, the forming of biocompatible medical devices with encapsulation and lubrication properties is related and analogous to the art of forming a piston for a syringe. Further there is nothing in the applicant's claims with limit PARYLENE being added only for lubrication. The teaching of forming with PARYLENE for encapsulation is proper and is fully capable of performing the lubrication features as well as all other PARYLENE capabilities. Even though the examiner cited a different problem solved

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through the Scheiner reference for adding PARYLENE. This addition would be fully capable of solving all claim limitations and applicants' lubrication arguments.

Therefore all rejections are proper, and all depending claims and rejections are proper. Claims 1-19 stand rejected, see below.

Specification

The use of the trademark PARYLENE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawa et al. (U.S. Patent Number 6,162,200). Sawa discloses a syringe and piston assembly that includes a piston (20), a piston rod (30), a first and second mating member with the same threaded pitch (see figure 2) that removably connect the rod to piston, and

annular ribs (21, 21a) extending radially from piston of differing edge radius (see figure 5). The Sawa threads have major and minor diameters, wherein the major and minor diameters of one of the first and second mating members are smaller than the major and minor diameters of the other of the first and second mating members. (see figures 2 and 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodworth et al. (U.S. Patent Application Number 2002/0139088) in view of Scheiner et al. (U.S. Patent Number 6,505,082). Woodworth et al. discloses a syringe assembly of a cyclic olefin polymer/bridged polycyclic olefin polymer barrel, a halogenated butyl rubber piston that is e-beam or steam sterilized. Woodworth discloses the claimed invention except for the parylene coating. Scheiner teaches that it is known to use parylene coating as set forth in paragraphs at column 35 through 37, to provide a non-thrombogenic encapsulate moisture barrier and insulate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the syringe assembly as taught by Woodworth with parylene coating as taught by Scheiner,

since such a modification would provide the syringe assembly with parylene coating for providing a non-thrombogenic encapsulate moisture barrier and insulate.

Claims 6-11, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodworth et al. in view of Scheiner et al. in further view of Sawa et al. (U.S. Patent Number 6,162,200). Woodworth in view of Scheiner discloses the claimed invention except for the threaded piston assembly with annular ribs. Sawa teaches that it is known to use a threaded piston assembly with annular ribs, as set forth in paragraphs beginning at column 1 through column 2, to provide a removable connectable plunger rod from piston. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the syringe assembly as taught by Woodworth in view of Scheiner with a threaded piston assembly with annular ribs as taught by Sawa, since such a modification would provide the syringe assembly with a threaded piston assembly with annular ribs for providing a removable connectable plunger rod from piston.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

